

| | |
|-----------------------------|--|
| Title | A clinical practice guideline for the management of patients with acute spinal cord injury: recommendations on the type and timing of rehabilitation |
| Authors | Fehlings, Michael G.;Tetreault, Lindsay A.;Aarabi, Bizhan;Anderson, Paul;Arnold, Paul M.;Brodke, Darrel S.;Chiba, Kazuhiro;Dettori, Joseph R.;Furlan, Julio C.;Harrop, James S.;Hawryluk, Gregory;Holly, Langston T.;Howley, Susan;Jeji, Tara;Kalsi-Ryan, Sukhvinder;Kotter, Mark;Kurpad, Shekar;Kwon, Brian K.;Marino, Ralph J.;Martin, Allan R.;Massicotte, Eric;Merli, Geno;Middleton, James W.;Nakashima, Hiroaki;Nagoshi, Narihito;Palmieri, Katherine;Singh, Anoushka;Skelly, Andrea C.;Tsai, Eve C.;Vaccaro, Alexander;Wilson, Jefferson R.;Yee, Albert;Burns, Anthony S. |
| Publication date | 2017 |
| Original Citation | Fehlings, M. G., Tetreault, L. A., Aarabi, B., Anderson, P., Arnold, P. M., Brodke, D. S., Chiba, K., Dettori, J. R., Furlan, J. C., Harrop, J. S., Hawryluk, G., Holly, L. T., Howley, S., Jeji, T., Kalsi-Ryan, S., Kotter, M., Kurpad, S., Kwon, B. K., Marino, R. J., Martin, A. R., Massicotte, E., Merli, G., Middleton, J. W., Nakashima, H., Nagoshi, N., Palmieri, K., Singh, A., Skelly, A. C., Tsai, E. C., Vaccaro, A., Wilson, J. R., Yee, A. and Burns, A. S. (2017) 'A clinical practice guideline for the management of patients with acute spinal cord injury: recommendations on the type and timing of rehabilitation', <i>Global Spine Journal</i> , 7(3S), pp. 231-238. doi: 10.1177/2192568217701910 |
| Type of publication | Article (peer-reviewed) |
| Link to publisher's version | http://journals.sagepub.com/doi/10.1177/2192568217701910 - 10.1177/2192568217701910 |
| Rights | © 2017, the Authors. This article is distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 License (http://www.creativecommons.org/licenses/by-nc-nd/4.0/) which permits non-commercial use, reproduction and distribution of the work as published without adaptation or alteration, without further permission provided the original work is attributed as specified on the SAGE and Open Access pages |

| | |
|----------------------|--|
| | (https://us.sagepub.com/en-us/nam/open-access-at-sage). - http://www.creativecommons.org/licenses/by-nc-nd/4.0/ |
| Download date | 2023-05-08 02:19:53 |
| Item downloaded from | http://hdl.handle.net/10468/5599 |



UCC

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

A Clinical Practice Guideline for the Management of Patients With Acute Spinal Cord Injury: Recommendations on the Type and Timing of Rehabilitation

Global Spine Journal
2017, Vol. 7(3S) 231S-238S
© The Author(s) 2017
Reprints and permission:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/2192568217701910
journals.sagepub.com/home/gsj


Michael G. Fehlings, MD, PhD, FRCSC, FACS^{1,2}, Lindsay A. Tetreault, PhD^{1,3}, Bizhan Aarabi, MD⁴, Paul Anderson, MD⁵, Paul M. Arnold, MD⁶, Darrel S. Brodke, MD⁷, Kazuhiro Chiba, MD, PhD⁸, Joseph R. Dettori, PhD, MPH⁹, Julio C. Furlan, MD, PhD^{2,10}, James S. Harrop, MD¹¹, Gregory Hawryluk, MD, PhD⁷, Langston T. Holly, MD¹², Susan Howley, BA¹³, Tara Jeji, MD¹⁴, Sukhvinder Kalsi-Ryan, PhD¹, Mark Kotter, PhD¹⁵, Shekar Kurpad, MD, PhD¹⁶, Brian K. Kwon, MD¹⁷, Ralph J. Marino, MD¹⁸, Allan R. Martin, MD¹, Eric Massicotte, MD¹, Geno Merli, MD¹⁹, James W. Middleton, HBBS, PhD²⁰, Hiroaki Nakashima, MD²¹, Narihito Nagoshi, MD^{1,22}, Katherine Palmieri, MD⁶, Anoushka Singh, PhD¹, Andrea C. Skelly, PhD⁹, Eve C. Tsai, MD, PhD²³, Alexander Vaccaro, MD, PhD¹¹, Jefferson R. Wilson, MD, PhD^{2,24}, Albert Yee, MD²⁵, and Anthony S. Burns, MD, PhD¹⁰

Abstract

Introduction: The objective of this study is to develop guidelines that outline the appropriate type and timing of rehabilitation in patients with acute spinal cord injury (SCI).

Methods: A systematic review of the literature was conducted to address key questions related to rehabilitation in patients with acute SCI. A multidisciplinary guideline development group used this information, and their clinical expertise, to develop recommendations for the type and timing of rehabilitation. Based on GRADE (Grading of Recommendation, Assessment, Development and Evaluation), a strong recommendation is worded as “we recommend,” whereas a weaker recommendation is indicated by “we suggest.”

Results: Based on the findings from the systematic review, our recommendations were: (1) We suggest rehabilitation be offered to patients with acute spinal cord injury when they are medically stable and can tolerate required rehabilitation intensity (no included

¹ Toronto Western Hospital, University Health Network, Toronto, Ontario, Canada

² University of Toronto, Toronto, Ontario, Canada

³ University College Cork, Cork, Ireland

⁴ University of Maryland School of Medicine, Baltimore, MD, USA

⁵ University of Wisconsin, Madison, WI, USA

⁶ The University of Kansas, Kansas City, KS, USA

⁷ University of Utah, Salt Lake City, UT, USA

⁸ National Defense Medical College, Saitama, Japan

⁹ Spectrum Research, Inc, Tacoma, WA, USA

¹⁰ Toronto Rehabilitation Institute, University Health Network, Toronto, Ontario, Canada

¹¹ Thomas Jefferson University, Philadelphia, PA, USA

¹² University of California at Los Angeles, Los Angeles, CA, USA

¹³ Christopher & Dana Reeve Foundation, Short Hills, NJ, USA

¹⁴ Ontario Neurotrauma Foundation, Toronto, Ontario, Canada

¹⁵ University of Cambridge, Cambridge, England

¹⁶ Medical College of Wisconsin, Milwaukee, WI, USA

¹⁷ University of British Columbia, Vancouver, British Columbia, Canada

¹⁸ Thomas Jefferson University Hospital, Philadelphia, PA, USA

¹⁹ Sidney Kimmel Medical College, Thomas Jefferson University Hospitals, Philadelphia, PA, USA

²⁰ University of Sydney, Sydney, New South Wales, Australia

²¹ Nagoya University Graduate School of Medicine, Nagoya, Japan

²² Keio University School of Medicine, Keio, Japan

²³ University of Ottawa, Ottawa, Ontario, Canada

²⁴ Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, Ontario, Canada

²⁵ Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada

Corresponding Author:

Michael G. Fehlings, MD, PhD, FRCSC, FACS, Division of Neurosurgery, Toronto Western Hospital, University Health Network, 399 Bathurst Street (SCI-CRU, 11th Floor McLaughlin Pavilion), Toronto, Ontario M5T 2S8, Canada.

Email: michael.fehlings@uhn.ca



studies; expert opinion); (2) We suggest body weight–supported treadmill training as an option for ambulation training in addition to conventional overground walking, dependent on resource availability, context, and local expertise (low evidence); (3) We suggest that individuals with acute and subacute cervical SCI be offered functional electrical stimulation as an option to improve hand and upper extremity function (low evidence); and (4) Based on the absence of any clear benefit, we suggest not offering additional training in unsupported sitting beyond what is currently incorporated in standard rehabilitation (low evidence).

Conclusions: These guidelines should be implemented into clinical practice to improve outcomes and reduce morbidity in patients with SCI by promoting standardization of care, decreasing the heterogeneity of management strategies and encouraging clinicians to make evidence-informed decisions.

Keywords

acute spinal cord injury, clinical guideline, guideline, rehabilitation, spinal cord injury, traumatic spinal cord injury

Summary of Recommendations

We suggest rehabilitation be offered to patients with acute spinal cord injury when they are medically stable and can tolerate required rehabilitation intensity.

Quality of Evidence: No included studies

Strength of Recommendation: Weak

We suggest offering body weight support treadmill training as an option for ambulation training in addition to conventional overground walking, dependent on resource availability, context, and local expertise.

Quality of Evidence: Low

Strength of Recommendation: Weak

We suggest that individuals with acute and subacute cervical spinal cord injury be offered functional electrical therapy as an option to improve hand and upper extremity function.

Quality of Evidence: Low

Strength of Recommendation: Weak

Based on the absence of any clear benefit, we suggest not offering additional training in unsupported sitting beyond what is currently incorporated in standard rehabilitation.

Quality of Evidence: Low

Strength of Recommendation: Weak

Introduction

Acute spinal cord injury (SCI) is a traumatic event that results in disturbances to normal sensory, motor or autonomic function and ultimately impacts a patient's physical, psychological and social well-being.¹ Rehabilitation primarily focuses on preventing secondary complications, promoting neurorecovery and maximizing function following injury. Other objectives include to improve a patient's independence in activities of daily living, to help a patient accept a new lifestyle and to facilitate community reintegration. Several rehabilitation strategies have been developed that focus on principles of motor control, activity-dependent neuroplasticity, and restoring function by remediating underlying impairments. Given the physical and psychological benefits of rehabilitation, it is critical to define the most appropriate strategies, including what techniques and exercises to use and the optimal timing of intervention.

This guideline provides evidence-based recommendations for the optimal type and timing of rehabilitation in patients with acute SCI. The ultimate goal of this guideline is to improve outcomes and reduce morbidity in patients with SCI by promoting standardization of care, encouraging clinicians to make more evidence-informed decisions and influencing policy changes to ensure adequate resource allocation. An introductory article in this focus issue provides further background information on SCI and summarizes the rationale, scope, and specific aspects of care covered by this guideline. This article is titled "A Clinical Practice Guideline for the Management of Acute Spinal Cord Injury: Introduction, Rationale, and Scope."

These guidelines are intended for use by neurologists, spine surgeons, physiatrists, sport medicine physicians, and rehabilitation specialists (including physiotherapists and occupational therapists).

Methods

This guideline was developed under the auspices of AOSpine North America, AOSpine International, and the American Association and Congress of Neurological Surgeons. A multidisciplinary guideline development group (GDG) was formed and consisted of clinicians from a broad range of specialties as well as patient advocates. The GDG was solely responsible for guideline development and was editorially independent from all funding sources. Members were required to disclose financial and intellectual conflicts of interest (Appendix, Chapter 2). A guideline development protocol, based on the Conference on Guideline Standardization (COGS) checklist^{2,3} was created to outline the rationale and scope of the guideline and to direct its development. Systematic reviews were conducted based on accepted methodological standards to summarize the evidence informing the recommendations. Details of specific methods used for each topic are outlined in the individual reviews included in this focus issue. Methods outlined by the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) Working Group were used to assess the overall quality (strength) of evidence for critical outcomes.^{4,5} The GRADE Guideline Development Tool was used to document the process, rank the importance of outcomes, weigh the benefits and harms of various options, and determine the strength of recommendations.⁶⁻⁹

Methodologists from Spectrum Research, Inc, worked closely with clinical authors to conduct the systematic reviews and provided methodological expertise on the guideline development process. Guideline development methods are provided in another article included in this focus issue: "Guidelines for the Management of Degenerative Cervical Myelopathy and Acute Spinal Cord Injury: Development Process and Methodology."

Part I. Timing of Rehabilitation in Patients With Acute Spinal Cord Injury

Population Description: Patients with acute spinal cord injury

Key Question: Should early (versus late) rehabilitation be recommended for individuals with acute or subacute spinal cord injury?

Recommendation 1: We suggest rehabilitation be offered to patients with acute spinal cord injury when they are medically stable and can tolerate required rehabilitation intensity.

Quality of Evidence: No included studies

Strength of Recommendation: Weak

Evidence Summary

A systematic review of the literature was conducted to address the following key questions: In adult patients with acute or subacute traumatic SCI, (1) Does the time interval between injury and commencing rehabilitation affect outcome? (2) What is the comparative effectiveness of different rehabilitation strategies, including different intensities and durations of treatment? (3) Are there patient or injury characteristics that impact the efficacy of rehabilitation? (4) What is the cost-effectiveness of various rehabilitation strategies?

No studies were identified that directly compared the impact of timing on the effectiveness of rehabilitation. Three (1 prospective, 2 retrospective) cohort studies reported that an increased time from injury to the initiation of rehabilitation was associated with declined activities of daily living and quality of life outcomes.¹⁰⁻¹² Two of these studies also evaluated the association between timing of rehabilitation and rehospitalization and pressure ulcers; one indicated a negative and the other a nonsignificant relationship.^{10,11}

Rationale for Recommendation

The outcomes most critical for decision making were improvement in neurologic outcomes, activities of daily living, ambulation, and quality of life. Other important outcomes to consider were reduced rates of mortality, rehospitalization, and secondary complications. The GDG unanimously agreed that there were no included studies that directly compared the efficacy and safety of early versus late rehabilitation and that any recommendation would be based on indirect evidence and/or clinical expert opinion.

The GDG unanimously agreed that there was no important uncertainty or variability about how much stakeholders value

the main outcomes. Clinicians and patients would similarly value improved neurologic outcomes, activities of daily living, ambulatory outcomes, quality of life and decreased risk of mortality, rehospitalization, and secondary complications. Payers would also value these outcomes given a likely reduction in overall costs.

The anticipated desirable effects are improved neurologic outcomes, activities of daily living, ambulation, and quality of life. Other anticipated desirable effects are reduced rates of mortality, rehospitalization and secondary complications. There are no studies that directly compared these outcomes between an early and late rehabilitation group. There were, however, retrospective cohort studies that reported that an increased time between injury and rehabilitation is associated with reduced function (activities of daily living) and quality of life.¹⁰⁻¹² There were also mixed reports whether timing of rehabilitation is associated with risk of rehospitalization or pressure ulcers.^{10,11} The GDG unanimously agreed that the anticipated desirable effects are probably large and indicated that other benefits to early rehabilitation include reduced burden on the health care system, decreased length of stay in acute care, and improved patient flow through the continuum of care. Furthermore, when confronted with a life-altering event such as a SCI, patients and individuals are understandably eager to initiate rehabilitation and begin working towards recovery as soon as possible. In this context, early rehabilitation would reduce the adverse psychological events that may occur due to delayed treatment.

The only foreseeable undesirable effect of early rehabilitation is increased transfers back to the acute care if the patient is not medically stable enough to tolerate the intensity of treatment. The GDG unanimously agreed that the anticipated undesirable effects are probably small and that the desirable effects are probably large relative to the undesirable effects.

In the absence of literature, the GDG used their clinical expertise to discuss the resources required for early versus late rehabilitation. Timing of rehabilitation is often dependent on bed availability, personal insurance coverage and other logistical factors. Furthermore, increased access to early rehabilitation would likely require a large financial and resource investment. The GDG unanimously agreed that the resource demand of early rehabilitation likely varies depending on the health care system and jurisdiction.

Unfortunately, the cost-effectiveness of early versus late rehabilitation is largely unknown. The GDG unanimously agreed that if the infrastructure was already established, then the resources required for early rehabilitation would not be significantly different than those required for late rehabilitation. Given that (1) there are likely no differences in costs between early versus late rehabilitation and (2) a longer interval to commencing rehabilitation is associated with worse performance of activities of daily living and quality-of-life-outcomes, the incremental cost is probably small relative to the net benefit. The GDG also unanimously agreed that there are costs associated with delaying entry into rehabilitation, including those associated with patient management in an acute care setting.

The GDG believed that a recommendation for early rehabilitation for patients with traumatic SCI would reduce health inequities if policy makers funded initiatives to ensure these patients had better access to care. Furthermore, the GDG selected that early rehabilitation would probably be an acceptable option to key stakeholders (all members of the GDG were in agreement). This decision was based on the potential benefits of early rehabilitation, low associated risk and resource requirements. Finally, the GDG unanimously agreed that the feasibility of early rehabilitation likely varies based on patient characteristics and health care systems.

Considering all these factors, the GDG voted that the desirable consequences probably outweigh the undesirable consequences in most settings (all members of the GDG were in agreement); this led to the formation of a weak recommendation for early rehabilitation in patients with traumatic SCI when they are medically stable and can tolerate the treatment intensity.

Part 2. Body Weight–Supported Treadmill Training in Patients With Acute or Subacute Spinal Cord Injury

Population Description: Patients with acute or subacute spinal cord injury

Key Question: Should body weight–supported treadmill training (versus conventional rehabilitation) be recommended for patients with acute or subacute spinal cord injury?

Recommendation 2: We suggest offering body weight–supported treadmill training as an option for ambulation training in addition to conventional overground walking, dependent on resource availability, context, and local expertise.

Quality of Evidence: Low

Strength of Recommendation: Weak

Evidence Summary

For key question 2, 5 studies were identified that evaluated the effectiveness of various rehabilitation strategies. Of these, 2 randomized controlled trials compared outcomes between patients treated with body weight–supported treadmill training (BWSTT) and those receiving conventional overground training.^{13,14}

Dobkin et al¹³ evaluated whether American Spinal Injury Association (ASIA) B, C, or D patients treated with BWSTT would have superior outcomes compared with a control group receiving defined overground mobility training of similar intensity. Based on their results, there were no significant differences between the groups with respect to Functional Independence Measure Locomotor (FIM-L) scores, Lower Extremity Motor Scores (LEMS), walking velocity or walking distance at 6 weeks, 3 months, 6 months, or 12 months. A second randomized controlled trial by Lucareli et al¹⁴ compared kinematic gait parameters (range of motion and spatial-temporal variables) between patients treated with BWSTT and those receiving conventional gait training. Both groups

underwent a total of 30 half-hour training sessions twice a week. Compared to the control group, patients receiving BWSTT achieved superior improvements in maximum hip extension during stance (mean difference from baseline: BWSTT, -0.2° ; Conventional, -7.8° ; $P < .001$) and maximum plantarflexion during preswing (mean difference from baseline: BWSTT, 0.0° ; Conventional, -9.7° ; $P < .001$).¹⁴ There were no differences between groups with respect to other range of motion variables, including dorsiflexion stance, knee extension stance, knee flexion swing and hip flexion while walking. BWSTT was more effective at improving spatial-temporal gait parameters (gait velocity, time of gait cycle, stance time/duration of support, swing time/balance duration, step length, distance, and cadence) than the control group.

In summary, there is low evidence that there is no difference between BWSTT and conventional rehabilitation with regard to the FIM-L score, LEMS, the distance walked in 6 minutes, or timed walk (m/s for 15.2 m) in patients with acute SCI.

Rationale for Recommendation

The outcomes most critical for decision making were change in FIM-L and LEMS scores. Distance walked in 6 minutes and timed walk (m/s for 15.2 m) were considered important but not critical outcomes. The strength of evidence related to these outcomes was rated as low; the relevant randomized controlled trials were downgraded for serious risk of bias and imprecision. The GDG unanimously agreed that the overall certainty of the evidence was low.

The GDG unanimously agreed that there was probably no important uncertainty or variability about how much stakeholders value the main outcomes. Clinicians and patients would similarly value improved FIM-L and LEMS scores. Payers would also value these outcomes given a likely reduction in overall management costs.

The anticipated desirable effects are improved FIM-L and LEMS scores, distance walked in 6 minutes, timed walk, angular kinematic parameters and spatial-temporal parameters. Based on the evidence, there are no differences between BWSTT and conventional rehabilitation with respect to FIM-L and LEMS scores, distance walked in 6 minutes, or timed walk. In contrast, improvements in spatial-temporal parameters, plantar flexion in preswing phase and hip extension during stance were significantly greater in the BWSTT treatment group. The GDG, however, was uncertain whether these effects are large and clinically relevant.

Based on clinical expertise, the GDG confirmed that there is no marked risk associated with BWSTT and that the undesirable anticipated effects of this treatment strategy are probably small (all members of the GDG were in agreement). As a result, the GDG were uncertain whether the desirable effects are large relative to the undesirable effects.

In the absence of literature, the GDG used their clinical expertise to discuss the resources required for BWSTT. The GDG unanimously agreed that the resources required for BWSTT are probably not small as it is a labor-intensive

approach that can require 2 to 3 therapists to manually assist the patient through the gait cycle. Unfortunately, there are no studies comparing the cost-effectiveness of BWSTT to conventional rehabilitation. However, given that (1) there is uncertain benefit of BWSTT and (2) there is a large resource requirement, the incremental cost is probably not small relative to the net benefit (all members of the GDG were in agreement).

The GDG believed that a recommendation for BWSTT for patients with traumatic SCI would reduce health inequities (all members of the GDG were in agreement). Furthermore, the GDG were uncertain whether this option would be acceptable to key stakeholders due to uncertain benefits and a large resource requirement. Finally, the GDG unanimously agreed that the feasibility of BWSTT likely varies based on patient characteristics and health care system.

Considering all these factors, the GDG voted that the desirable and undesirable consequences are closely balanced or uncertain in most settings (all members of the GDG were in agreement); this led to the formation of a weak recommendation for BWSTT in patients with traumatic SCI that is dependent on resource availability, context, and local expertise.

Part 3. Functional Electrical Therapy in Patients With Acute or Subacute Spinal Cord Injury

Population Description: Patients with acute or subacute spinal cord injury

Key Question: Should functional electrical therapy (versus conventional rehabilitation) be recommended for patients with acute or subacute spinal cord injury?

Recommendation 3: We suggest that individuals with acute and subacute cervical SCI be offered functional electrical therapy as an option to improve hand and upper extremity function.

Quality of Evidence: Low

Strength of Recommendation: Weak

Evidence Summary

For key question 2, 2 randomized controlled trials evaluated outcomes following functional electrical stimulation (FES) versus conventional therapy.^{15,16}

A study by Popovic et al¹⁵ compared outcomes between patients treated with FES and occupational therapy and those treated with only occupational therapy. Based on their results, the FES group exhibited significantly greater improvements on the FIM Motor subscore (15.0 vs 4.1 points), FIM Self-Care subscore (20.1 vs 10 points) and Spinal Cord Independence Measure (SCIM) Self-Care subscore (10.2 vs 3.1 points) than the control group.¹⁵ FES was also significantly more effective than the control therapy at improving 2 of the 9 components of the Toronto Rehabilitation Institute Hand Function Test: (1) the ability to hold an instrumented cylinder and (2) the ability to hold a credit card.¹⁵ A second randomized controlled trial by Kohlmeyer et al¹⁶ evaluated the effectiveness of FES,

biofeedback and a combination of these treatments versus conventional strengthening therapy for recovering tenodesis grasp. Based on their results, there were no significant differences between treatment groups in terms of tenodesis grasp.

In summary, there is low evidence suggesting that, compared with conventional occupational therapy, FES results in (1) an 11.3-point increase in FIM Motor subscore, (2) a 10.4-point increase in FIM Self-Care subscore, (3) a 5.7-point increase in SCIM Self-Care subscore; and (4) an improved ability to hold a cylinder and credit card.

Rationale for Recommendation

The outcomes most critical for decision making were change in FIM Motor subscore, FIM Self-Care subscore and SCIM Self-Care subscore. The Toronto Rehabilitation Institute Hand Function Test was considered an important but not a critical outcome. The strength of evidence related to these outcomes was rated as low; the relevant randomized controlled trials were downgraded for serious risk of bias and imprecision. The GDG unanimously agreed that the overall certainty of the evidence was low.

The GDG unanimously agreed that there was probably no important uncertainty or variability about how much stakeholders value the main outcomes. Clinicians and patients would similarly value improved FIM Motor, FIM Self-Care, and SCIM Self-Care subscores. Payers would also value these outcomes given a likely reduction in overall management costs.

The anticipated desirable effects are improved FIM motor, FIM Self-Care, and SCIM Self-Care subscores. Based on the evidence, patients treated with functional electrical therapy exhibit greater improvements in FIM Motor, FIM Self-Care, and SCIM Self-Care subscores than those receiving conventional occupational therapy. The GDG unanimously agreed that the desirable anticipated effects were probably large.

Based on clinical expertise, the GDG confirmed that there is no marked risk associated with functional electric therapy and that the undesirable anticipated effects of this strategy are probably small (all members of the GDG were in agreement). As a result, the GDG unanimously agreed that the desirable effects are probably large relative to the undesirable effects.

In the absence of literature, the GDG used their clinical expertise to discuss the resources required for functional electrical therapy. The GDG unanimously agreed that the resources required for this treatment are probably small as the equipment is relatively inexpensive and the training is not more extensive than what is typically required to learn a new technique. Unfortunately, there are no studies comparing the cost-effectiveness of functional electrical therapy versus conventional rehabilitation. However, given that (1) there is a potentially large benefit of functional electrical therapy and (2) the resources required are probably small, the incremental cost is probably small relative to the net benefit.

The GDG believed that a recommendation for functional electrical therapy would reduce health inequities if policy makers fund initiatives to ensure patients with traumatic SCI have better access to this type of treatment (all members of the GDG

were in agreement). Furthermore, the GDG unanimously agreed that this option is probably acceptable to key stakeholders due to potential benefits and low risks; however, given the uncertainty surrounding the cost-effectiveness of this treatment, it is uncertain whether this option would be acceptable to payers. Finally, the GDG believed that functional electrical therapy is likely feasible to implement given a low resource and training requirement (all members of the GDG were in agreement).

Considering all these factors, the GDG voted that the desirable consequences probably outweigh undesirable consequences in most settings (all members of the GDG were in agreement); this led to the formation of a weak recommendation for functional electrical therapy in patients with traumatic SCI to improve hand and upper extremity function.

Part 4. Training Unsupported Sitting in Patients With Acute or Subacute Spinal Cord Injury

Population Description: Patients with acute or subacute spinal cord injury

Key Question: Should training unsupported sitting (versus control/standard in-patient therapy) be recommended for patients with acute or subacute spinal cord injury?

Recommendation 4: Based on the absence of any clear benefit, we suggest not offering additional training in unsupported sitting beyond what is currently incorporated in standard rehabilitation.

Quality of Evidence: Low

Strength of Recommendation: Weak

Evidence Summary

A single randomized controlled trial was identified that compared outcomes between patients who received additional training time devoted to unsupported sitting exercises and those treated with standard in-patient therapy.¹⁷ Based on their results, the predetermined “minimally worthwhile treatment effect” was not achieved on any of the outcome measures, including the SCI Falls Concern Scale, maximal lean test and the Canadian Occupational Performance Measure (COPM).¹⁷ In summary, there is low evidence suggesting there are no added benefits of unsupported sitting training.

Rationale for Recommendation

The GDG unanimously agreed that none of the reported outcomes were critical for decision making. The maximal lean test and sideward reach test were considered important but not critical outcomes. The evidence for this recommendation was derived from a randomized controlled trial by Harvey et al, which had no serious indirectness and undetected publication bias. Consistency of these findings, however, was unknown and the estimates of effect were imprecise. The GDG unanimously agreed that the overall certainty of the evidence was low.

The GDG unanimously agreed that there was possibly important uncertainty or variability about how much stakeholders value the main outcomes, especially the payers. None of the reported outcomes (maximal lean test, maximal sideward reach test, t-shirt test, scores on SCI Falls Concern scale, COPM, COPM satisfaction, or participants’/clinicians’ impression of change) were considered critical for decision making and therefore may be less valued by key stakeholders.

The anticipated desirable effects are improved maximal lean test and maximal sideward test. Based on the evidence, there were no clinically meaningful differences between treatment groups with respect to the maximal lean test, maximal sideward reach test, t-shirt test, scores on SCI falls concern scale, COPM, COPM satisfaction or participants’/clinicians’ impression of change. The GDG unanimously agreed that the anticipated desirable effects are not large.

Based on clinical expertise, the GDG confirmed that there is no marked risk associated with training unsupported sitting and that the undesirable anticipated effects of this strategy are probably small. The GDG unanimously agreed that the desirable effects are probably not large relative to the undesirable effects.

In the absence of literature, the GDG used their clinical expertise to discuss the resources required to train unsupported sitting. The GDG unanimously agreed that the resources required to train unsupported sitting are probably not significantly larger than those needed for standard inpatient therapy. Unfortunately, there are no studies comparing the cost-effectiveness of training unsupported sitting versus standard inpatient therapy. The GDG believed that it is uncertain whether the incremental costs are small relative to the net benefits given (1) the desirable effects are probably not large relative to the undesirable effects and (2) the resources required are probably small (all members of the GDG were in agreement).

The GDG believed that a recommendation for training unsupported sitting would reduce health inequities. However, the GDG unanimously agreed that this option is probably not acceptable to key stakeholders given limited benefits and unknown cost-effectiveness of this treatment. Finally, the GDG believed that training unsupported sitting is likely feasible to implement given a low resource requirement (all members of the GDG were in agreement).

Considering all these factors, the GDG voted that the desirable and undesirable consequences are closely balanced or uncertain (all members of the GDG were in agreement); this led to the formation of a weak recommendation against additional training of unsupported sitting beyond what is currently incorporated in standard rehabilitation.

Evidence Gaps and Future Research Recommendations

This guideline has identified important knowledge gaps in the literature and areas of future research. These include (1) a lack of studies directly evaluating the impact of timing of treatment on the effectiveness of rehabilitation; (2) limited certainty as to

what constitutes a clinically important change for a number of the outcome measures studied; (3) uncertainty surrounding the size of anticipated desirable effects, the impact of our recommendations on health inequities, the acceptability of various options to key stakeholders and the feasibility of implementation; and (4) limited evidence on the cost-effectiveness of various rehabilitation strategies. Furthermore, the level of evidence for most of our findings was low, suggesting that we have limited confidence in the estimate of effect and that the true effect may be substantially different; further research is required to confirm these conclusions.

Our findings were based on randomized controlled trials or nonrandomized observational studies that controlled for injury severity. We have identified significant limitations in the current body of evidence, including (1) variability across studies with respect to the patient population, type of rehabilitation, therapeutic doses and outcome measures assessed; (2) small sample sizes for certain comparisons; (3) the effect estimates were often imprecise; and (4) the majority of studies did not meet one or more criteria of a good randomized controlled trial (eg, random sequence generation, statement of concealed allocation, intention to treat, adequate sample size, complete follow-up of $\geq 80\%$ and controlling for potential confounding) or observational study (eg, study design, patients at a similar point in the course of their disease or treatment, complete follow-up of $\geq 80\%$, and patients followed long enough for outcomes to occur).

Because of the nature of rehabilitation research, it is difficult to determine the impact and superiority of individual treatments.¹⁸ In addition to the limitations noted above, other identified issues include superimposed spontaneous recovery, problems with group assignment and active contrast for control groups and the fact that contemporary rehabilitation typically involves the simultaneous application of several treatments by multiple team members.¹⁸ It is anticipated that there will continue to be significant barriers and ethical concerns to performing comparative studies (and withholding specific rehabilitation services). When confronted with a life-altering event such as a SCI, patients are understandably eager to initiate rehabilitation early and train towards regaining function using a variety of techniques. Furthermore, there is typically great pressure to transition patients from acute care to rehabilitation as soon as feasible; this is driven by a need to minimize costs associated with acute care and maintain patient flow and resource availability.

As a result, new methodologies are required to study early and delayed rehabilitation interventions and to build our knowledge on the optimal timing, prescription and dosing of rehabilitative strategies following SCI.

Implementation Considerations

It is expected that this guideline will influence clinical practice and facilitate evidence-based decision making. Dissemination of the knowledge from this guideline is of critical importance and will be accomplished at multiple levels:

- Presentation at international spine surgery, critical care, neurology, anesthesiology, and vascular medicine conferences
- Scientific and educational courses in symposium format
- Webinar dissemination of information to a broad audience in an interactive format
- Publication of a focus issue in a peer-reviewed journal
- Submission to the National Guideline Clearinghouse
- AOSpine International Spinal Cord Injury Knowledge Forum

Potential barriers to implementation include:

1. Some centers will not have access to the equipment needed for BWSTT or FES. Furthermore, BWSTT is a labor intensive approach that can require substantial resources, including 2 to 3 therapists to manually assist the patient through the gait cycle.
2. Initiating early rehabilitation is dependent on access to rehabilitation facilities and patient flow through the continuum of care.

Internal Appraisal and External Review of This Guideline

Vice-chairs of the GDG conducted an internal appraisal of the final guideline using Appraisal of Guidelines for Research & Evaluation II (AGREE II) standards.¹⁹ A multidisciplinary group of stakeholders, including patients, were invited to externally review the final draft prior to publication. Additional details of these processes are found in the accompanying methods article.

Plans for Updating

The guidelines will be reviewed by the primary sponsor and the vice-chairs at 3 years to a maximum of 5 years following publication. The guideline will be updated when new evidence suggests the need to modify our recommendations. An earlier update will be considered if there are changes in (1) the evidence related to harms and benefits, (2) outcomes that would be considered important for decision making, (3) ranking of current critical and important outcomes, and (4) available interventions and resources.

Authors' Note

Guideline Development Committee Members: Co-Chair, Michael G. Fehlings, MD PhD, Neurosurgery; Co-Chair: James Harrop, MD, Neurosurgery; Vice-Chair: Jefferson R. Wilson, MD, PhD, Neurosurgery; Vice-Chair: Anthony Burns, MD, Physical Medicine/Rehabilitation; General Member of Leadership Group: Brian Kwon, MD, PhD, Orthopedic Surgery; Systematic Review Coordinator: Lindsay Tetreault, PhD, Research.

Acknowledgments

The GDG would like to acknowledge the funding of AOSpine North America, International, and the AANS/CNS. In particular, we would

like to thank Chi Lam, Kelly McCormick, Nancy Holmes and Maria Alvarez for their assistance and for organizing our meetings. We were grateful for the opportunity to collaborate with Spectrum Research, Inc, and would like to thank Krystle Pagarigan and Eric Schnell for their administrative support.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This research was supported by AOSpine, the Ontario Neurotrauma Foundation (ONF) and the AANS/CNS Section on Neurotrauma and Critical Care. Dr Fehlings wishes to acknowledge support from the Gerald and Tootsie Halbert Chair in Neural Repair and Regeneration and the DeZwirek Family Foundation. Dr Tetreault acknowledges support from a Krembil Postdoctoral Fellowship Award. Methodological support was provided by Spectrum Research, Inc.

References

1. Singh A, Tetreault L, Kalsi-Ryan S, Nouri A, Fehlings MG. Global prevalence and incidence of traumatic spinal cord injury. *Clin Epidemiol*. 2014;6:309-331. doi:10.2147/CLEP.S68889.
2. Shiffman RN, Michel G. Toward improved guideline quality: using the COGS statement with GEM. *Stud Health Technol Inform*. 2004;107:159-163.
3. Shiffman RN, Shekelle P, Overhage JM, Slutsky J, Grimshaw J, Deshpande AM. Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization. *Ann Intern Med*. 2003;139:493-498.
4. Balshem H, Helfand M, Schunemann HJ, et al. GRADE guidelines: 3. Rating the quality of evidence. *J Clin Epidemiol*. 2011;64:401-406.
5. Agency for Healthcare Research and Quality. *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (AHRQ Publication No. 10(14)-EHC063-EF). Rockville, MD: Agency for Healthcare Research and Quality; 2013.
6. Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: the significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66:719-725. doi:10.1016/j.jclinepi.2012.03.013.
7. Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66:726-735. doi:10.1016/j.jclinepi.2013.02.003.
8. Schunemann HJ, Oxman AD, Akl EA, et al. Moving from evidence to developing recommendations in guidelines: article 11 in integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. *Proc Am Thorac Soc*. 2012;9:282-292. doi:10.1513/pats.201208-064ST.
9. Wu JC, Ko CC, Yen YS, et al. Epidemiology of cervical spondylotic myelopathy and its risk of causing spinal cord injury: a national cohort study. *Neurosurg Focus*. 2013;35:E10. doi:10.3171/2013.4.FOCUS13122.
10. Teeter L, Gassaway J, Taylor S, et al. Relationship of physical therapy inpatient rehabilitation interventions and patient characteristics to outcomes following spinal cord injury: the SCIREhab project. *J Spinal Cord Med*. 2012;35:503-526. doi:10.1179/2045772312y.0000000058.
11. Whiteneck G, Gassaway J, Dijkers MP, Heinemann AW, Kreider SE. Relationship of patient characteristics and rehabilitation services to outcomes following spinal cord injury: the SCIREhab project. *J Spinal Cord Med*. 2012;35:484-502. doi:10.1179/2045772312y.0000000057.
12. Abdul-Sattar AB. Predictors of functional outcome in patients with traumatic spinal cord injury after inpatient rehabilitation: in Saudi Arabia. *NeuroRehabilitation*. 2014;35:341-347.
13. Dobkin B, Barbeau H, Deforge D, et al. The evolution of walking-related outcomes over the first 12 weeks of rehabilitation for incomplete traumatic spinal cord injury: the multicenter randomized Spinal Cord Injury Locomotor Trial. *Neurorehabil Neural Repair*. 2007;21:25-35. doi:10.1177/1545968306295556.
14. Lucareli PR, Lima MO, Lima FP, de Almeida JG, Brech GC, D'Andréa Greve JM. Gait analysis following treadmill training with body weight support versus conventional physical therapy: a prospective randomized controlled single blind study. *Spinal Cord*. 2011;49:1001-1007.
15. Popovic MR, Kapadia N, Zivanovic V, Furlan JC, Craven BC, McGillivray C. Functional electrical stimulation therapy of voluntary grasping versus only conventional rehabilitation for patients with subacute incomplete tetraplegia: a randomized clinical trial. *Neurorehabil Neural Repair*. 2011;25:433-442. doi:10.1177/1545968310392924.
16. Kohlmeyer KM, Hill JP, Yarkony GM, Jaeger RJ. Electrical stimulation and biofeedback effect on recovery of tenodesis grasp: a controlled study. *Arch Phys Med Rehabil*. 1996;77:702-706.
17. Harvey LA, Ristev D, Hossain MS, et al. Training unsupported sitting does not improve ability to sit in people with recently acquired paraplegia: a randomised trial. *J Physiother*. 2011;57:83-90.
18. Dobkin BH. Confounders in rehabilitation trials of task-oriented training: lessons from the designs of the EXCITE and SCILT multicenter trials. *Neurorehabil Neural Repair*. 2007;21:3-13. doi:10.1177/1545968306297329.
19. Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 2: assessment of validity of items and tools to support application. *CMAJ*. 2010;182:E472-478. doi:10.1503/cmaj.091716.